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June 23, 2006

MEMORANDUM

TO: Administrators of Nursing Homes, Community Residential Care Facilities, Residential Treatment Facilities for Children and Adolescents

FROM: Dennis L. Gibbs, Director
Division of Health Licensing

SUBJECT: Provider-Wide Exception – Tuberculosis Screening for Employees/Staff Members/Volunteers and Residents

§ B.(4)(b). of S.C. Regulation 61-17, *Standards for Licensing Nursing Homes*, requires that, "On employment and no more than three months prior to employment, all new employees, volunteers and private sitters who have contact with residents shall have a physical examination which shall include a tuberculin skin test, unless a previously positive reaction can be documented..."

In addition, § D.(3)(c) of S.C. Regulation 61-17, *Standards for Licensing Nursing Homes*, requires that, "Within one month prior to admission, all first time residents shall have a physical examination including a two-step tuberculin skin test unless they have been documented to have been a previously positive reactor..."

§ 1702.B. of S.C. Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, requires that, "Staff members/direct care volunteers of facilities shall be required to have evidence of a two-step tuberculin skin test within three months prior to resident contact..."

In addition, § 1702.B.3. of S.C. Regulation 61-84 requires that, "Residents shall have at least the first step within the period for completion of the admission physical examination as specified in Section 1101 (within 30 days prior to admission)..."

§ C.(5)(a) of S.C. Regulation 61-103, *Standards for Licensing Residential Treatment Facilities for Children and Adolescents*, requires that, "All new employees who have contact with residents shall have a physical examination prior to employment, which shall include a tuberculin skin test, unless a previously positive reaction can be documented..."

In addition, § D.(2)(a)(1)(a)(10) of S.C. Regulation 61-103 requires that, "The residential treatment facility is responsible for a complete assessment of the resident, some of which may be required just prior to admission, by reliable professionals acceptable to the facility's staff. The complete assessment shall include, but is not limited to... Tuberculosis screening."

The above sections of the regulations delineate tuberculosis control activities for employees and residents in these facilities. Such activities include testing procedures, positive reactions, tuberculosis exposure, and treatment.

The Centers for Disease Control & Prevention (CDC) has recently published *Guidelines for Preventing Transmission of* Mycobacterium tuberculosis *in Health-Care Settings*, 2005. Although a majority of tuberculosis control topics remain unchanged, there are some updates that relate to tuberculosis risk assessment, setting up a tuberculosis program, tuberculosis screening, two-step tuberculosis procedures, evidence of potential on-going transmission, and tuberculosis problem evaluation. The Department has reviewed this CDC tuberculosis guideline and has developed Department tuberculosis guidelines. These guidelines impact current regulations. To summarize, there is an expansion of the types of TB testing available that facilities may utilize and, as determined by a facility's risk assessment, *i.e.*, "Low Risk" or "Medium Risk", the frequency of TB testing may vary. Relevant Departmental TB guidelines are attached as an addendum.

Therefore, in the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the residents of nursing homes, community residential care facilities, and residential treatment facilities for children and adolescents, it has been determined that alternative standards will be considered as acceptable.

All nursing homes, community residential care facilities, and residential treatment facilities for children and adolescents will be required to meet the standards outlined in the regulations, *i.e.*, R61-17, §§ B.(4)(b) and D.(3)(c); R61-84, §§ 1702.B. and 1702.B.3..; R61-103, §§ C.(5)(a) and D.(2)(a)(1)(a)(10), or, as an alternative:

Tuberculosis screening shall be performed in the manner designated by Department TB guidelines in § IV of the attached addendum, including following the procedure for conducting a risk assessment as detailed in § III of the addendum.

For informational purposes, §§ I and II have been added to the addendum and include references and definitions.

This exception applies to any nursing home, community residential care facility, or residential treatment facility for children and adolescents licensed by the Department. This exception relates solely to SC licensing standards. Any adverse condition(s) that may be related to this exception may result in revocation of the exception by the Department.

If there are any questions regarding the exception, please contact Randy Clark or Shelton Elliott of the Division of Health Licensing at (803) 545-4370 and questions concerning the content of the addendum or other Department TB guidelines, please call the Department's Division of TB Control at (803) 898-0558.

DLG/rel

cc: C. Earl Hunter, Commissioner, DHEC
Pam Dukes, DHEC
Randy Clark, DHEC
Shelton Elliott, DHEC
Nancy Layman, DHEC
Karen Price, DHEC
Shea Rabley, DHEC TB

Enclosure

June 23, 2006

ADDENDUM

Nursing Homes, Community Residential Care Facilities, Residential Treatment Facilities for Children and Adolescents

Tuberculosis Screening Guidelines Recommended by CDC and Established by DHEC

SECTION I. References

CDC Guidelines for Preventing Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. *MMWR* Vol. 54, No. RR-17, December 30, 2005. http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

SECTION II. Definitions

A. Airborne Infection Isolation (AII): A room designed to maintain Airborne Infection Isolation, formerly called a negative pressure isolation room. An Airborne Infection Isolation room is a single-occupancy resident-care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. Airborne Infection Isolation rooms shall provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of 6–12 air changes per hour (ACH), and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter.

B. Blood Assay for *Mycobacterium tuberculosis* (BAMT): A general term to refer to recently-developed in vitro diagnostic tests that assess for the presence of infection with *M. tuberculosis*. This term includes, but is not limited to, IFN-γ release assays (IGRA). In the United States, the currently available test is QuantiFERON®-TB Gold test (QFT-G).

C. Contact Investigation: Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection (LTBI) or TB disease, and treatment of these persons, as indicated.

D. Healthcare Worker (HCW): All paid persons (employees, staff) and unpaid persons (volunteers) working in the healthcare setting who have the potential for exposure to *M. tuberculosis* through air space shared with persons with infectious pulmonary TB disease.

E. Latent TB Infection (LTBI): Infection with *M. tuberculosis*. Persons with Latent TB Infection carry the organism that causes TB but do not have TB disease, are asymptomatic, and are noninfectious. Such persons usually have a positive reaction to the tuberculin skin test.

F. Tuberculin Skin Test (TST): A diagnostic aid for detecting *M. tuberculosis* infection. A small dose (0.1 mil) of purified protein derivative (PPD) tuberculin is injected just beneath the surface of the skin (by the Mantoux method), and the area is examined for induration (hard, dense, raised area at the site of Tuberculin Skin Test (TST) administration) by palpation 48–72 hours after the injection (but positive reactions can still be measurable up to a week after Tuberculin Skin Test (TST) administration). The size of the indurated area is measured with a millimeter ruler after identifying the margins transverse (perpendicular) to the long axis of the forearm. The reading is recorded in millimeters, including 0 mm to represent no induration. Redness/erythema is insignificant and is not measured or recorded.

G. Two-Step Testing: Procedure used for the baseline skin testing of persons who may periodically receive Tuberculin Skin Tests (TST) to reduce the likelihood of mistaking a boosted reaction for a new infection. If the initial Tuberculin Skin Test (TST) result is interpreted as negative, a second test is repeated 1-3 weeks after the initial test. If the initial Tuberculin Skin Test (TST) result is interpreted as positive, then the reaction shall be documented and followed up as positive; this reaction will serve as the baseline and no further skin testing is indicated. If the second test is given and its result is interpreted as positive, then the reaction shall be documented and followed up as positive; this reaction will serve as the baseline reading and no further skin testing is indicated. In general, the result of the second Tuberculin Skin Test (TST) of the two-step procedure shall be used as the baseline reading.

SECTION III. Risk Assessment For Settings In Which Residents With Suspected Or Confirmed TB Disease Are Not Expected To Be Encountered

A. The initial and ongoing risk assessment for these settings shall consist of the following steps (use of applicable elements of the TB risk assessment worksheets found as Appendix B in the CDC Guidelines for Preventing Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. *MMWR* Vol. 54, No. RR-17, December 30, 2005 at http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf may be helpful):

1. Review the community profile of TB disease in collaboration with the local or state health department;

2. Consult the local or state TB control program to obtain epidemiologic surveillance data necessary to conduct a TB risk assessment for the healthcare setting (available on the DHEC website at http://www.scdhec.gov/health/disease/tb);

3. Determine if persons with unrecognized TB disease were encountered in the setting during the previous 5 years;

4. Determine if any healthcare workers (*i.e.*, employees, staff, volunteers) need to be included in the TB screening program;

5. Determine the types of environmental controls that are currently in place, and determine if any are needed in the setting;

6. Document procedures that ensure the prompt recognition and evaluation of suspected episodes of healthcare-associated transmission of *M. tuberculosis*;

7. Conduct periodic reassessments at least annually to ensure 1) proper implementation of the TB infection control plan; 2) prompt detection and evaluation of suspected TB cases; 3) prompt initiation of airborne precautions of suspected infectious TB cases before transfer; 4) prompt transfer of suspected infectious TB cases; 5) proper functioning of environmental controls, as applicable; and 6) ongoing TB training and education for healthcare workers (*i.e.*, employees, staff, volunteers);

8. Recognize and correct lapses in infection control.

B. The risk classification shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for healthcare workers (*i.e.*, employees, staff, volunteers) and residents and the frequency of screening (CDC TB Guidelines, Appendix C). A risk classification shall be determined for the entire setting. However, in certain settings (*e.g.*, healthcare organizations that encompass multiple sites or types of services), specific areas defined by geography, functional units, patient population, job type, or location within the setting might have separate risk classifications.

SECTION IV. TB Testing Requirements For Settings In Which Residents With Suspected or Confirmed TB Disease Are Not Expected To Be Encountered

A. Healthcare Workers (*i.e.*, employees, staff, volunteers)

1. Low Risk

a. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All healthcare workers (*i.e.*, employees, staff, volunteers) (within 3 months prior to contact with residents) unless there is a documented Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) result during the previous 12 months. If a newly employed healthcare worker (*i.e.*, employee, staff, volunteer) has had a documented negative Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) result within the previous 12 months, a single Tuberculin Skin Test (TST) (or the single Blood Assay for *Mycobacterium tuberculosis* (BAMT)) can be administered in the new setting to serve as the baseline there.

b. Serial (periodic) Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT): Not indicated (not required).

c. Post-exposure Tuberculin Skin Tests (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) for healthcare workers (*i.e.*, employees, staff, volunteers) upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) as soon as possible to all healthcare workers (*i.e.*, employees, staff, volunteers) who have had unprotected exposure to an infectious TB case/suspect. If the Tuberculin Skin Test (TST) or the Blood Assay for *Mycobacterium tuberculosis* (BAMT) result is negative, administer another Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) 8-10 weeks after that exposure to *M. tuberculosis* ended.

2. Medium Risk

a. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All healthcare workers (*i.e.*, employees, staff, volunteers) (within 3 months prior to contact with residents) unless there is a documented Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) result during the previous 12 months. If a newly employed healthcare worker (*i.e.*, employee, staff, volunteer) has had a documented negative Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) result within the previous 12 months, a single Tuberculin Skin Test (TST) (or the single Blood Assay for *Mycobacterium tuberculosis* (BAMT)) can be administered in the new setting to serve as the baseline.

b. Serial (periodic) testing (with Tuberculin Skin Test (TST) or Blood Assay for *Mycobacterium tuberculosis* (BAMT)): Annually, of all healthcare workers (*i.e.*, employees, staff, volunteers) who have risk of TB exposure and who have previous documented negative results. Instead of participating in serial (periodic) testing, healthcare workers (*i.e.*, employees, staff, volunteers) with documented TB infection (positive Tuberculin Skin Test (TST) or Blood Assay for *Mycobacterium tuberculosis* (BAMT)) shall receive a symptom screen annually. This screen shall be accomplished by educating the healthcare worker (*i.e.*, employee, staff, volunteer) about symptoms of TB disease (including the healthcare workers (*i.e.*, employees, staff, volunteers) responses), documenting the questioning of the healthcare worker (*i.e.*, employee, staff, volunteer) about the presence of symptoms of TB disease, and instructing the healthcare worker (*i.e.*, employee, staff, volunteer) to report any such symptoms immediately to the administrator or director of nursing. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC/DHEC guidelines and, if recommended, treatment completion shall be encouraged.

c. Post-exposure Tuberculin Skin Tests (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) for healthcare workers (*i.e.*, employees, staff, volunteers) upon unprotected exposure to *M. tuberculosis*: Perform a contact

investigation when unprotected exposure is identified. Administer one Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) as soon as possible to all healthcare workers (*i.e.*, employees, staff, volunteers) who have had unprotected exposure to an infectious TB case/suspect. If the Tuberculin Skin Test (TST) or the Blood Assay for *Mycobacterium tuberculosis* (BAMT) result is negative, administer another Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) 8-10 weeks after that exposure to *M. tuberculosis* ended.

3. Baseline Positive or Newly Positive Test Result

a. Healthcare workers (*i.e.*, employees, staff, volunteers) with a baseline positive or newly positive test result for *M. tuberculosis* infection (*i.e.*, Tuberculin Skin Test (TST) or Blood Assay for *Mycobacterium tuberculosis* (BAMT)) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis (*e.g.*, cough, weight loss, night sweats, fever, *etc.*) shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy within the previous 3 months). These healthcare workers (*i.e.*, employees, staff, volunteers) will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (*i.e.*, DHEC TB Control program).

b. Healthcare workers (*i.e.*, employees, staff, volunteers) who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a licensed physician, and permitted to return to work ONLY with approval by the DHEC TB Control program. Repeat chest radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a physician.

B. Residents

1. For Low Risk and Medium Risk

a. Admission/Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All residents within one month prior to admission unless there is a documented Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) result during the previous 12 months. If a newly-admitted resident has had a documented negative Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) result within the previous 12 months, a single Tuberculin Skin Test (TST) (or the single Blood Assay for *Mycobacterium tuberculosis* (BAMT)) can be administered within one month prior to admission to this facility to serve as the baseline. In the institutional nursing home setting, residents admitted from other parts of that institutional campus who have had TB screening done which meets the requirements outlined in this section and which was done within the last six months will not be required to undergo additional initial screening.

b. Serial (periodic) Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT): Not indicated (not required).

c. Post-exposure Tuberculin Skin Tests (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) for residents upon unprotected exposure to ***M. tuberculosis***: Perform a contact investigation when unprotected exposure is identified. Administer one Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) as soon as possible to all residents who have had exposure to an infectious TB case/suspect. If the Tuberculin Skin Test (TST) or the Blood Assay for *Mycobacterium tuberculosis* (BAMT) result is negative, administer another Tuberculin Skin Test (TST) or a Blood Assay for *Mycobacterium tuberculosis* (BAMT) 8-10 weeks after that exposure to ***M. tuberculosis*** ended.

2. Baseline Positive or Newly Positive Test Result

a. Residents with a baseline positive or newly positive test result for ***M. tuberculosis*** infection (***i.e.***, Tuberculin Skin Test (TST) or Blood Assay for *Mycobacterium tuberculosis* (BAMT)) or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis (***e.g.***, cough, weight loss, night sweats, fever, *etc.*) shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy within the previous 3 months). Routine repeat chest radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a physician. These residents will be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and will be encouraged to follow the recommendations made by a physician with TB expertise (***i.e.***, DHEC TB Control program).

b. Residents who are known or suspected to have TB disease shall be transferred from the facility if the facility does not have an Airborne Infection Isolation room, required to undergo evaluation by a licensed physician, and permitted to return to the facility ONLY with approval by the DHEC TB Control program.